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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,565	10/11/2001	Catherine S. Levisage	55322 (71699)	7490
21874	7590	12/29/2004	EXAMINER	
EDWARDS & ANGELL, LLP			FUBARA, BLESSING M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1615

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,565

Applicant(s)

LEVISAGE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,37-42,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,14-20,37-42,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, request for extension of time, amendment and remarks, all filed 12/07/04. Claims 1-20, 37-42, 52 and 53 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 12/07/04 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-11, 14-20, 37-42, 52 and 53 rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. (US 6,211,273).

Bru-Magniez discloses a nanoparticles of polymeric support material network within which therapeutic agents such as taxol and 5-fluorouracil are dispersed (abstract, column 2, lines 35-50, column 5, lines 3-35 and column 6, lines 25-36). The disclosed polymer network meets the polymer structure of the instant claims and the prior art specifically discloses methyldiene malonate nanoparticles (column 2, lines 15-17 and Title). The instant method comprises

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administering the polymeric composition. The prior art administers the composition orally, sublingually, subcutaneously, intramuscularly, intravenously, transdermally, locally, rectally, via the pulmonary route, or nasally; preferred forms of administration notably comprise oral forms, such as tablets, gelatin capsules, powders, granules and oral solutions or suspensions, sublingual and buccal administration forms, as well as subcutaneous, intramuscular intravenous, intranasal or intraocular and rectal administration forms (column 6, lines 43-53). It is inherent that the administered composition comprising an anticancer drug would inherently provide the desired effect. The nanoparticles of Bru-Magniez have diameter of less than 500 nm and particles having diameter of 100-500 nm are preferred (column 3, line 67 to column 4 line 1). The method of preparing the particles of Bru-Magniez involves preparing a solution of the polymer in a water miscible organic solvent, adding with stirring, the organic phase to an aqueous polymerization medium at a pH between 4.5 and 10, homogenizing the mixture, evaporating the organic solvent in vacuo to recover/collect the nanoparticles (column 4, lines 5-13). In another embodiment, the polymer precipitates in the polymerization medium, the polymer is recovered by filtration and the suspension or filtrate of the nanoparticles is "conditioned and lyophilized" (column 4, lines 14-36). It is noted that the process of recovering precipitates by filtration routinely involves wash cycle(s).

Bru-Magniez discloses the composition and method for preparing the composition. The difference between the prior art and the instant claims is the size of the particles. The prior art discloses particle diameter of less than 500 nm, which is 0.5 μm . The amended claim now has a lower limit of 1.0 μm and applicants' specification and the remarks provide no demonstration that a microparticle having a mean particle diameter of about 1.0 μm provides unusual results. A

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mean particle diameter of about 1.50 μ m is not critical over a mean particle diameter of less than 0.5 μ m in the absence of a showing of criticality. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nanoparticle of Bru-Magniez. One having ordinary skill in the art would have been motivated to prepare nanoparticles of methylidene malonate having a diameter of less than 500 nm or 100-500 nm with the expectation that the medicament dispersed within the polymer is delivered to a subject.

Applicants argue that the instant claims are directed to microparticles having mean particle size of between 1.0 μ m and 100 μ m while the prior art discloses nanoparticles having average particle size of less than 500 nm, which is 0.5 μ m. Applicants then contend that the Bru-Magniez does not teach any method of treatment.

Response to Arguments

4. Applicants' arguments filed 12/07/04 have been fully considered but they are not persuasive.

Examiner recognizes that the range of the particle size of the prior art is outside the range of the particle size of the instant claim. However, Examiner takes the position that both the prior art and the instant claims are in the same field of endeavor solving the same problem. The particles of the prior art are used for applicants' purpose. Applicants provided no evidence that a particles size of 1.0 μ m is a critical and unusual limitation in applicants' polymeric composition. The treatment method comprises administration and the composition of the prior art administered would have the same effect.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name and title.